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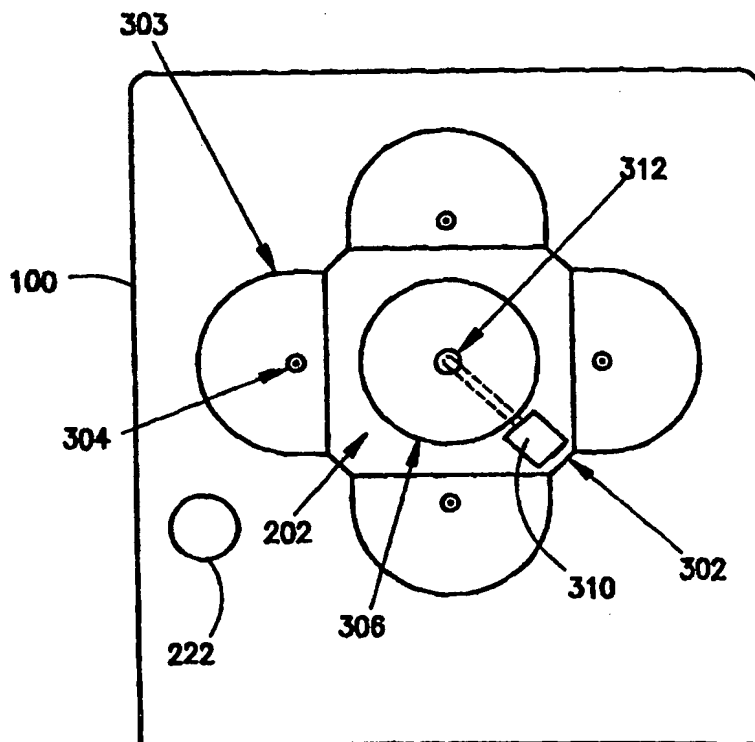
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(54) Title: SYSTEM AND METHOD FOR STERILIZING OBJECTS

## (57) Abstract

A system (100) for sterilizing objects is disclosed wherein within a chamber (202) an ultraviolet light source (304) is used to apply ultraviolet light to an object to which a chromophore-containing solution has been applied, the chromophore-containing solution being activated by the ultraviolet light (304) to effectively destroy bacteria and other micro-organisms on the object. The chromophore-containing solution is preferably applied via an atomizer which atomizes the solution and applies the resulting fog to the object. Hydrogen peroxide (222) is preferably applied in a like manner. In a preferred embodiment, the ultraviolet light source is a UV-B light source. The presence of the chromophore on the item to be sterilized enhances absorption of the UV-B radiation by micro-organisms, and thus substantially enhances the effectiveness of the sterilization process. Chromophores which may be used in accordance with the invention include, e.g., butyl methoxydibenzoylmethane and avobenzene/octyl methoxycinnamate. The wavelength of the light applied is preferably selected in conjunction with the chromophore for maximum efficacy.



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## SYSTEM AND METHOD FOR STERILIZING OBJECTS

This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/087,160 filed May 29, 1998, the entire disclosure of which is incorporation herein by reference.

### Field of the Invention

The present invention relates generally to systems and methods for sterilizing objects using ultraviolet irradiation to activate a chromophore-containing solution which effectively destroys bacteria and other micro-organisms.

### Background of the Invention

There is a long-felt need to eliminate micro-organisms from a variety of objects, from medical instruments to foodstuffs. Various methods have been used to provide the desired sterilization of these items, including heat, chemicals, and nuclear irradiation.

Ultraviolet irradiation is another long-recognized method of sterilizing objects. For example, the inventor's prior U.S. Patent 5,120,499 discloses a method and system for asepticizing contact lenses. The lenses are placed in a liquid medium such as water, saline, hydrogen peroxide, or solutions of saline and methox salen. The lenses are irradiated with ultraviolet radiation of (typically) between 290 and 310 nm. The radiation tends to reduce the hydrogen peroxide to its constituent free radicals, which are  $H_2$  and  $OH$ . These free radicals tend to reconstitute to form  $H_2O$  and  $O_2$ . However, this patent does not suggest the use of a chromophore for sterilization, and the system is designed particularly for contact lenses and not adapted for other purposes.

Ultraviolet radiation has been used for sterilization of other items such as fruit, but is only effective on the surfaces it reaches. UV-C radiation has been considered for this purpose, but may have a carcinogenic or mutagenic effect on such organic materials. UV-C is absorbed by most materials, and will undesirably alter the molecular structure of materials that absorb it.

Therefore, there is a general need for improved methods and systems for sterilization of objects and foodstuffs.

### Summary of the Invention

The invention according to a preferred embodiment includes a system and method for sterilizing objects wherein an ultraviolet light source is used to apply ultraviolet light to an object to which a chromophore-containing solution has been applied, the chromophore-containing solution being activated by the ultraviolet light to effectively destroy bacteria and other micro-organisms on the object. The chromophore-containing solution is preferably applied via an atomizer which atomizes the solution and applies the resulting fog to the object. Hydrogen peroxide is preferably applied in a like manner. In a preferred embodiment, the ultraviolet light source is a UV-B light source. The presence of the chromophore on the item to be sterilized enhances absorption of the UV-B radiation by micro-organisms, and thus substantially enhances the effectiveness of the sterilization process. Chromophores which may be used in accordance with the invention include, e.g., butyl methoxydibenzoylmethane and avobenzene/octyl methoxycinnamate. The wavelength of the light applied is preferably selected in conjunction with the chromophore for maximum efficacy, i.e. in the identified wavelength range to which the chromophore responds.

Brief Description of the Drawings

The foregoing and other objects, features, and advantages of the invention will be apparent from the following more particular description of preferred embodiments as illustrated in the accompanying drawings, in which reference characters refer to the same parts throughout the various views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating principles of the invention.

Figure 1 is a top view of one embodiment of an apparatus for sterilizing instruments according to the present invention;

Figure 2 is a side sectional view of the sterilizing apparatus of Figure 1;

Figure 3 is a top sectional view of the apparatus of Figure 1, showing the arrangement of UV lighting and a receptacle for items to be sterilized;

Figure 4 is a block schematic diagram of a control and operating circuit according to the present invention;

Figure 5 is a flowchart showing one embodiment of the sterilization process according to the invention;

Figure 6a is a side sectional view of another embodiment of a medical instrument asepticizing chamber according to the present invention;

Figure 6b is a perspective view of a hydroxyl delivery system according to the invention;

Figure 6c is a side view showing operation of the hydroxyl delivery system of Figure 6b; and

Figure 7 is a side sectional view of an asepticizing chamber designed according to the invention, configured for fresh produce disinfection and packaging.

### Detailed Description of the Preferred Embodiments

The present invention provides an improved method and system for sterilizing objects which can be applied to a variety of objects using apparatus of appropriate size and orientation. The invention will be explained first with reference to an exemplary apparatus appropriate for sterilizing medical instruments and the like, and further with reference to a system for destruction of microorganisms on a variety of objects, including fruit and other foodstuffs. However, those skilled in the art will recognize that these systems and techniques may be applied to a variety of organic and inorganic items.

Figure 1 is a top view of one preferred embodiment of an apparatus for sterilizing instruments. Sterilizer 100 has a top surface 101, in which a door 102 and a reservoir access port 104 are provided. Controls 106 and an associated display 108 are provided for control and monitoring of system operation. The controls may include a keyboard and/or a plurality of control switches.

Figure 2 is a side sectional view of the device of Figure 1, which illustrates the arrangement of significant operating components of sterilizer 100. As can be seen, door 102 is provided with a handle 105 and is hinged to provide access to sterilization chamber 202. Chamber 202 has a drain 206 leading to a drip tray 208 which drains into waste tank 210. Waste tank 210 has access ports 212 for draining waste material from tank 210. Pump 214 is connected by tubing 216 to filters 218, which are connected by tubing 220 to reservoir 222. Reservoir 222 may be filled with hydrogen peroxide.

Pump 214 is connected by tubing 224 to a solenoid valve 226, and then by

soft tubing 228 to a distributor 230 at the top of chamber 202. Distributor 230 restricts flow of the hydrogen peroxide, applying it at a pressure of approximately 0.5 atm. Distributor 230 also atomizes the hydrogen peroxide to ensure that peroxide enters any cavities on the device to be sterilized. Distributor 230 may be customized for the item to be sterilized, and provided with directed distribution ports aimed at particular parts of the item (such as cavities) which might not otherwise be fully coated with the peroxide.

In operation, when solenoid valve 226 and pump 214 are actuated, hydrogen peroxide may be drawn from reservoir 222 and distributed in atomized form over items placed in chamber 202. The hydrogen peroxide solution used is preferably in the range of a 1% to 40% solution, depending on the desired sterility and the sensitivity of the item to be sterilized to hydrogen peroxide application. For example, for foodstuffs such as fruits and vegetables, low concentrations are preferable, such as within a range of 1% to 3%. For sterilizing instruments, higher percentages may be used.

Optionally, one or more heating/cooling fans 204 may be provided. Warming may be desirable to the extent that it helps atomize the peroxide. However, to conserve energy, the warming provided should be at a level which assists in atomizing the peroxide but is not bactericidal.

Figure 3 is a top sectional view of sterilizer 100 showing the configuration of chamber 202. Chamber 202 comprises enclosure shield 302 which surrounds chamber 202. Enclosure shield 302 is UV-transparent and seals light sources 304 against contact with materials introduced into chamber 202, such as the hydrogen peroxide. Chamber 202 is provided with a spin gear 312 connected to a spin motor 310 for selectively rotating a carousel 306. Carousel 306 may be loaded either with a basket or with a custom-fitted holding device for the item to be sterilized.

The portions around the periphery of chamber 202, and particularly

reflectors 303, are lined with a material that reflects UV-B light, such as etched aluminum, and may be provided with additional reflectors, optics, and optical waveguides to ensure that the UV light reaches particular desired areas. For example, a jig may be constructed to hold a device such as an endoscope, and provided with optical fibers or other light guide mechanisms to collect and transmit the UV light to crevices, and other critical portions of the endoscope.

Figure 4 is a block schematic diagram showing the control system of the present invention. A microprocessor 400 is connected to receive signals from controls 106 and to display operating status information on display 108. Microprocessor 400 is connected to control and monitor the following devices: flow control 226, blower/heater 204, pump 214, spin motor 308, UV light source 304, and condition sensors 402 which may include temperature, position, and other feedback control sensors appropriate as inputs to control algorithms for implementing the operating features described herein. An operating program stored in a nonvolatile memory of the microprocessor defines an automated control sequence or "cycle" for implementing the sterilization operating process disclosed herein.

The operating process and a preferred sequence of solution and radiation applications will now be described in more detail with reference to Figure 5. Significantly, in the preferred embodiment, a chromophore is applied to the item to be sterilized during the sterilization process. The chromophore used may be Parsol MCX (TM) (butyl methoxydibenzoylmethane), which has been found to particularly absorb UV-C and UV-B in the 250 nm to 310 nm wavelength range, or Parsol 1789 (TM) (avobenzene/octyl methoxycinnamate), which has been found to particularly absorb UV-B and UV-A, in the 290-380 nm wavelength range. Parsol 1789 (TM) and Parsol MCX (TM) are manufactured by Givaudan-Roure Corp of Clifton, New Jersey. The wavelength of the light applied is preferably selected in conjunction with the chromophore for maximum efficacy, i.e. in the identified wavelength range to which the chromophore responds. The chromophore is preferably applied by methods and structures similar to those



disclosed for application of the hydrogen peroxide to the materials to be sterilized. Preferably, the chromophore is applied as a fog. The presence of the chromophore on the item to be sterilized enhances absorption of the UV-B radiation by micro-organisms, and thus substantially enhances the effectiveness of the sterilization process.

The radiation applied by the light source is preferably UV-B radiation, as opposed to UV-C radiation. Most preferably, the radiation has a wavelength in the range from 290 nm to 320 nm. The light source may be a UV-B lamp manufactured by North American Philips. More preferably, a pulsed laser is used to provide a collimated UV light source. An example of appropriate lasers are XeCl lasers with a wavelength of 308 nm and a maximum pulse energy of 2.0 mJ, with a maximum peak power of 800 kW (at 50 Hz) and a maximum average power of 150 mW (at 100 Hz). A pulse duration of 2.5 ns may be used, with the pulses continuously applied for an effective period to provide the desired sterilization.

The use of a pulsed laser is preferred over a lamp because it is easier to control the amount of energy dispersed against the item to be sterilized when using a laser. The pulse rhythm of the laser effectively breaks down the hydrogen peroxide and activates the chromophore to enhance absorption of UV-B radiation by any microorganisms present.

In operation, preferably there is an alternating sequence of applications of solutions and radiation as shown in Figure 5. First, a chromophore is applied to the item to be sterilized (block 504), and UV-B radiation is applied to the chromophored item (block 506). Hydrogen peroxide is then applied (block 508), and UV-B radiation applied to the hydrogen peroxide and the item. (block 510). Finally, a sterile normal saline rinse is applied (block 512) to remove any remaining solutions and contaminants.

As an alternative, the above noted chromophore application step (block

504) may be performed with the chromophore applied to the item as part of a saline solution. It is also possible to replace the above-noted chromophore application step with an application of standard saline without a chromophore, while still meeting requirements for some sterilization operations.

An alternative embodiment of the medical instrument asepticizing device according to the present invention is shown in Figure 6a. An asepticizing chamber 602 comprises UV-B lamps 604, beamsplitter ports 606, fogging ports 608, and instrument mounting ports 614. Chamber exterior surfaces 612 are made of UV-B reflecting material such as polished aluminum or stainless steel. Interior support surfaces 610 are made of UV-B transparent material such as glass or a plastic.

Beamsplitter ports 606 are connected via a fiber optic beamsplitting and transmission connection to one or more central UV-B lasers. Preferably, a pulsed laser is used to provide a collimated UV light source. One example of an appropriate laser is an XeCl laser with a wavelength of 308 nm and a maximum pulse energy of 2.0 mJ, with a maximum peak power of 800 kW (at 50 Hz) and a maximum average power of 150 mW (at 100 Hz). A pulse duration of 2.5 ns may be used, with the pulses continuously applied for an effective period to provide the desired sterilization. Ports 608 may have an optical termination that emits the laser light into a proximate cloud of hydrogen peroxide or other fog emitted from fogging ports 608. Alternatively, ports 608 may receive a flexible fiber optic cable 616 which transmits the laser light available at the port to an optical termination at the end of fiber optic cable 616. Fiber optic cable 616 may be used to transmit the UV-B light into relatively inaccessible parts of the items to be sterilized which may harbor bacteria, such as "dead legs" of endoscopes 618.

Fogging ports 608 are connected to a fog generating apparatus which selectively draws from one or more reservoirs of material to be applied to the items in the chamber. For sterilization purposes, the fogging ports 608 will emit a fog of hydrogen peroxide at a predetermined concentration, preferably between 1 percent and 30 percent. Fogging ports 608 may be used for multiple types of fog,

or a separate set of ports, reservoir, and fogging apparatus may be provided for different materials to be applied. The fogs to be applied include, in addition to hydrogen peroxide, chromophores and rinses as described elsewhere in the specification.

Instrument mounting ports 614 are provided in suitable configurations to engage cavities of the instruments or other items to be sterilized. These ports provide an integrated combination fogger and light source. Instrument mounting port 614 is shown in more detail in Figure 6b. Instrument mounting port 614 has an annular fogging port 622 around its circumference which is connected to the unit's fog generator. In the center of instrument mounting port 614, there is a laser output port 623 which is connected via fiber optic cable and a beamsplitter to the unit's UV-B laser source. The instrument mounting port 614 illustrated in Figure 6b is sized to engage an end of endoscope 618 (shown in Figure 6a). In operation, instrument mounting port 614 fills the internal portion of the endoscope with a hydrogen peroxide fog, and activates the fog with UV-B light from laser output port 623.

Referring again to Figure 6a, when the system is in operation, endoscopes 618 or other items to be sterilized are placed in chamber 602. Fogging ports 608 and beamsplitter ports 606 are activated as shown in Figure 6c to fill chamber 602 with a fog 624 of hydrogen peroxide, which is then illuminated by the UV-B light from lamps 604 and/or ports 606 and cables 616 to produce  $\text{OH}^+$  and  $\text{H}_2^+$ , which as a result become the byproducts  $\text{H}_2\text{O}$  and  $\text{O}_2$ . Finally, as shown in Figure 6a, water and other non-gaseous byproducts are drained from chamber 602 through drains 620.

Environmental pressure may be increased within the asepticizing chambers shown herein during operation, to force the asepticizing materials into cavities or "dead legs" in the instruments to be disinfected.

Figure 6c is a side view showing operation of the hydroxyl delivery system

of Figure 6b. A hydrogen peroxide fog emanates from the hydroxyl delivery systems. When illuminated by a UV-B laser or fluorescent UV-B light source, the fog breaks down into OH- and H<sub>2</sub>+ which then combine to form byproducts H<sub>2</sub>O and O<sub>2</sub>.

Figure 7 is a side sectional view of an asepticizing chamber 700 according to the present invention, configured for fresh produce disinfection and packaging. As in the embodiment of Figure 6a, ports 606 and 608 are provided to apply laser light and hydroxyl-containing fog to chamber 700 in the same manner described previously with reference to Figure 6c. UV-B lamps 604 of up to 50,000 watts per lamp are also provided. A "tumbling" conveyor belt 702 carries produce 704 through chamber 700 while continually exposing different sides of the produce.

The sides 708 of chamber 700 are lined with UV-B reflective material, while the conveyor itself is preferably of UV-B transmitting material so that UV-B light reflected from underneath the conveyor is applied to the underside of the produce. Byproduct drains 706 are provided to remove water and other liquid byproducts.

A conventional automated packing device 710 is placed to receive the output of chamber 700 and produce packaged asepticized produce.

In operation, chamber 700 provides a hydrogen peroxide fog at a concentration of from 1 percent to 30 percent, but preferably less than 3%. This fog is activated by UV-B light from lamps 604, or from a UV-B laser through ports 606, or by both, to asepticize the produce, generally in the manner described previously. A final rinse of sanitized water may optionally be provided to remove any traces of hydrogen peroxide from the produce. The final rinse may be applied by stopping the conveyor and applying rinse water through the chamber's fogging apparatus, or in a separate rinse stage (not shown). The application of a rinse is desirably avoided where possible, because of the possibility that rinse water might reintroduce bacteria to the produce.

Thus, there has been disclosed both an improved apparatus and an improved method for sterilizing instruments, foodstuffs, and other items. While the invention has been particularly shown and described with reference to a preferred embodiment thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An apparatus for sterilizing an object, comprising:
  - an ultraviolet light source for applying ultraviolet light to said object;
  - a reservoir containing a chromophore-containing solution; and,
  - means for applying said chromophore-containing solution to said object, said chromophore-containing solution being activated by said ultraviolet light to effectively destroy bacteria and other micro-organisms on said object.
2. The apparatus according to claim 1, wherein said means for applying further comprises means for applying hydrogen peroxide.
3. The apparatus according to claim 1, wherein said means for applying comprises an atomizer for atomizing said chromophore-containing solution and applying a resulting fog to said object.
4. The apparatus according to claim 1, further comprising a chamber for receiving an object to be sterilized
5. The apparatus according to claim 4, further comprising an enclosure shield of UV-transparent material surrounding said chamber for sealing said light source from contact with said chromophore-containing solution.

6. The apparatus according to claim 1, wherein said ultraviolet light source comprises a UV-B light source.

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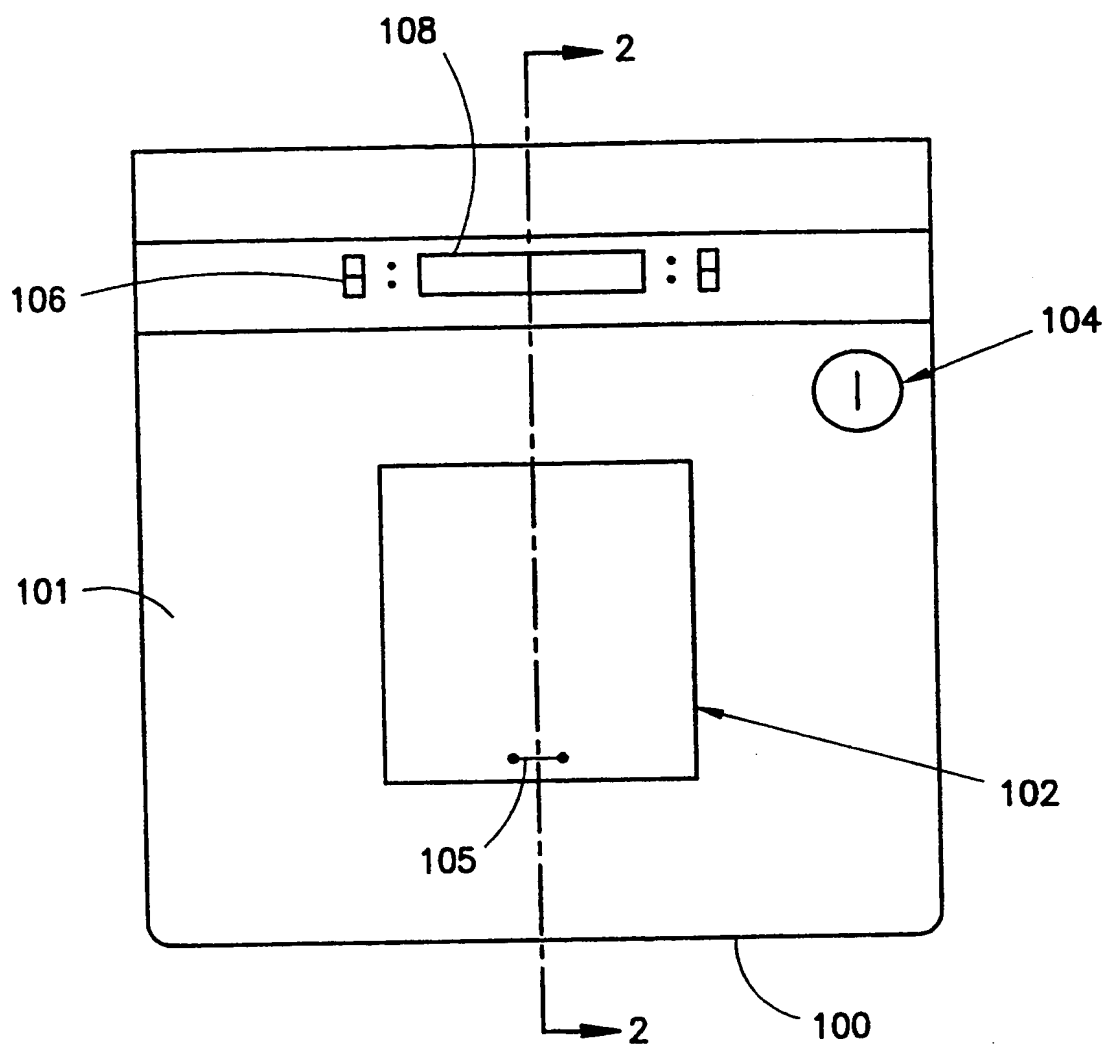


FIG. 1



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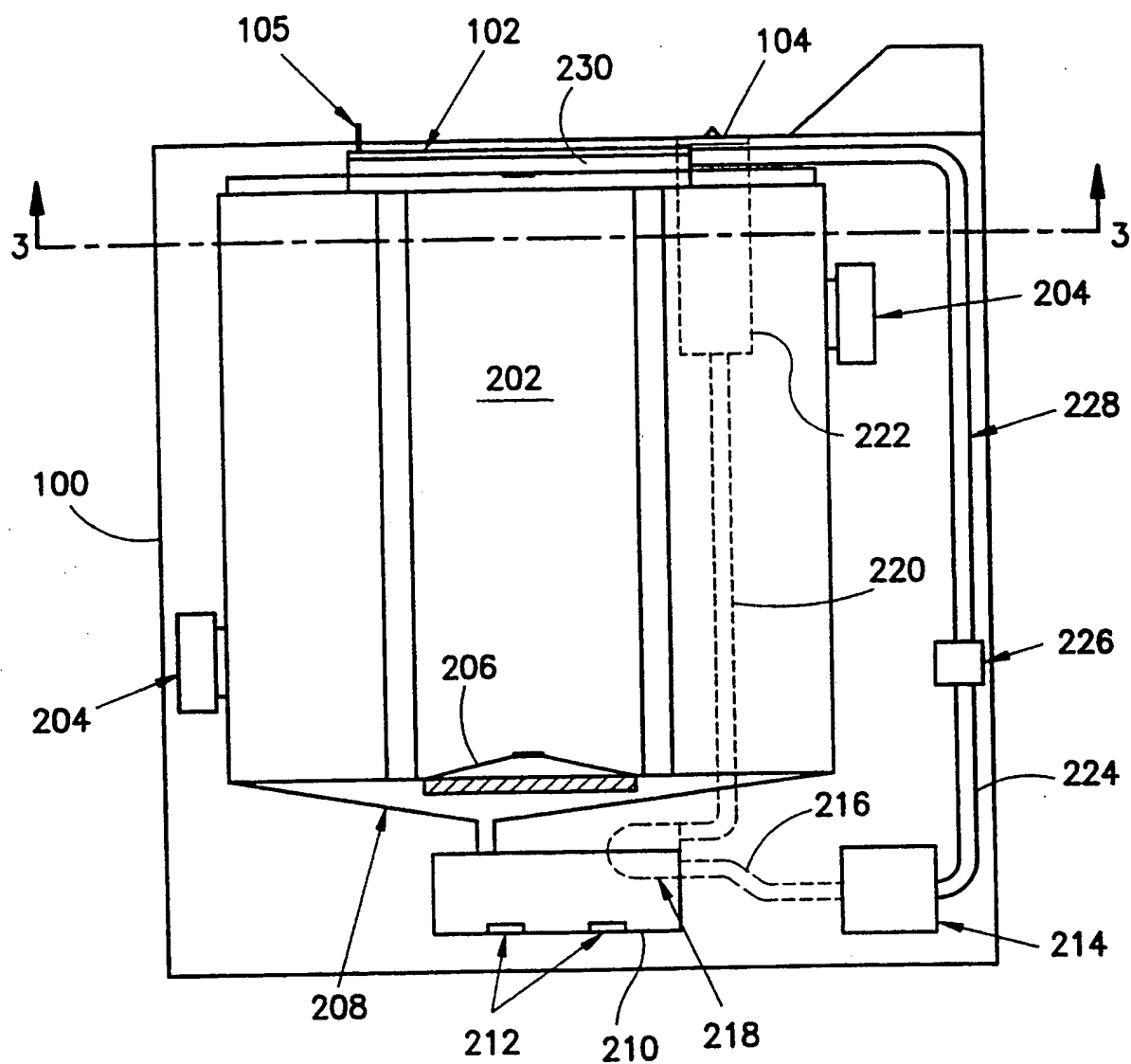


FIG. 2

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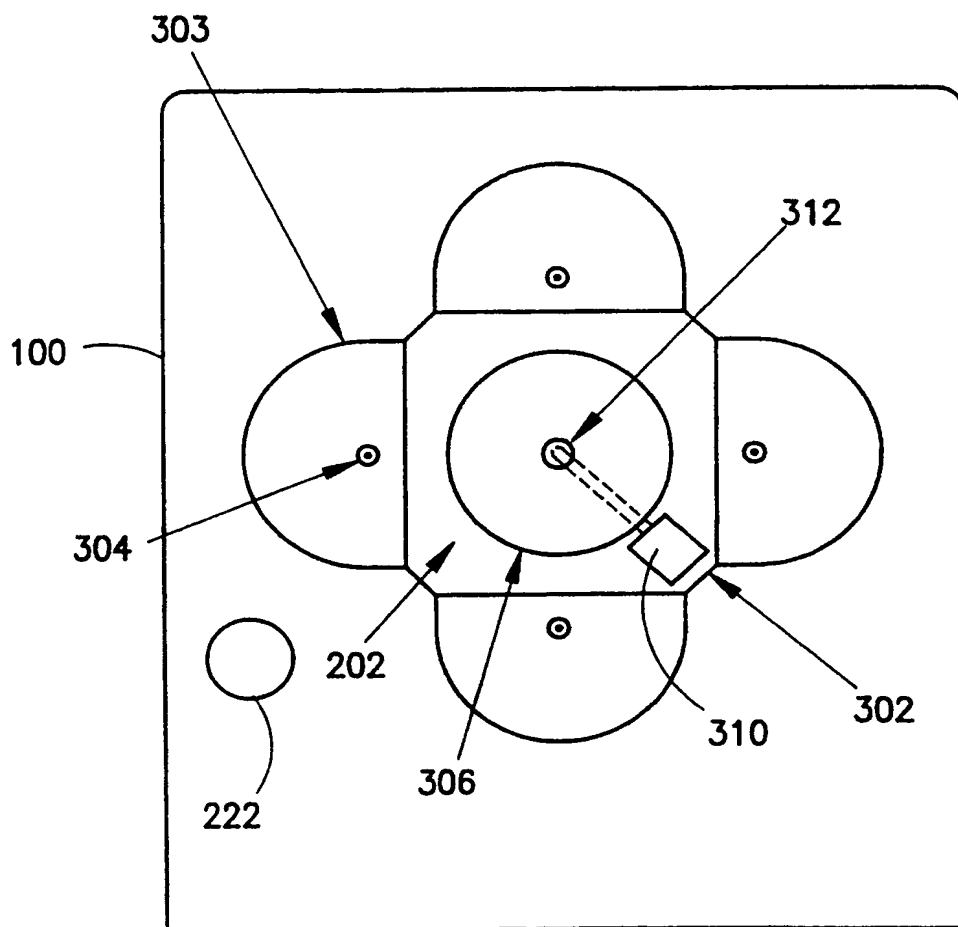


FIG. 3

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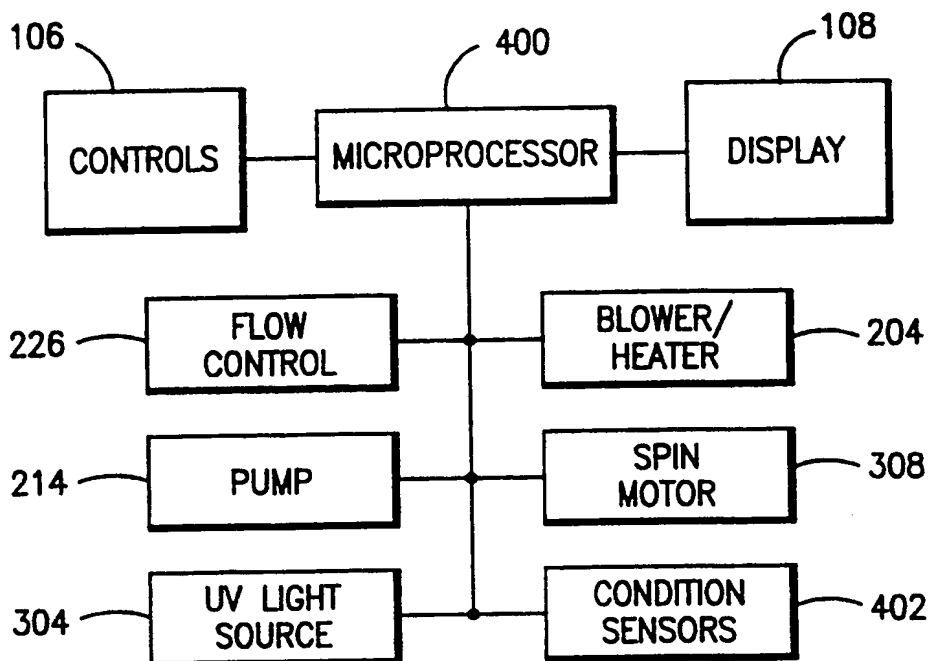
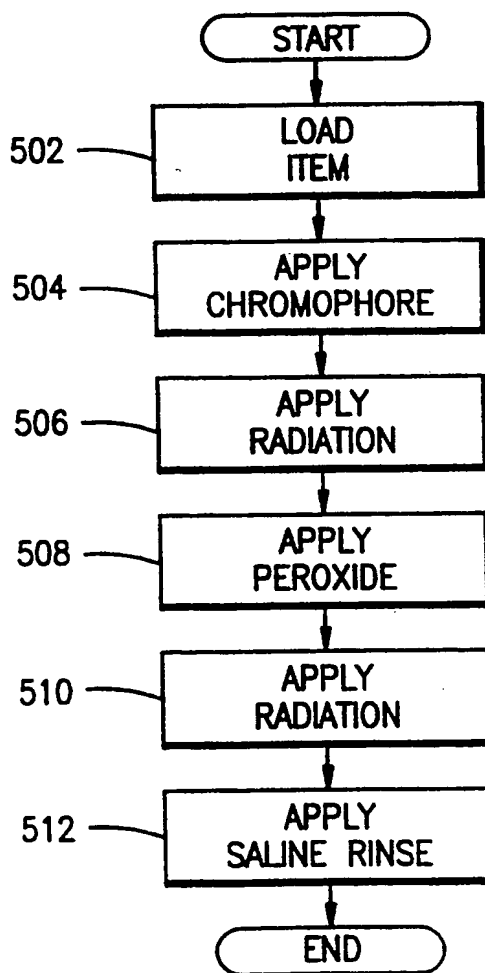


FIG. 5



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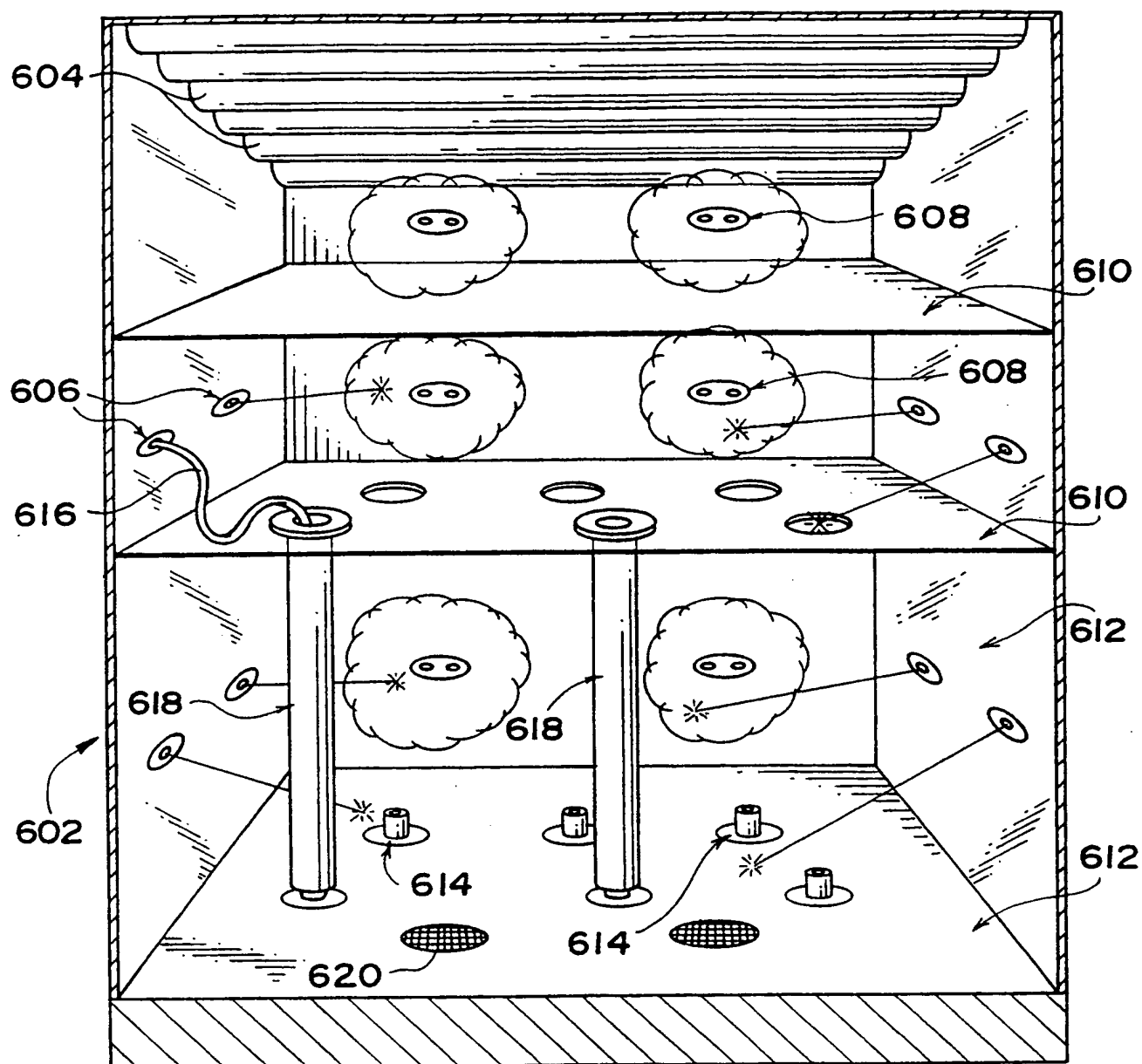


FIG. 6a

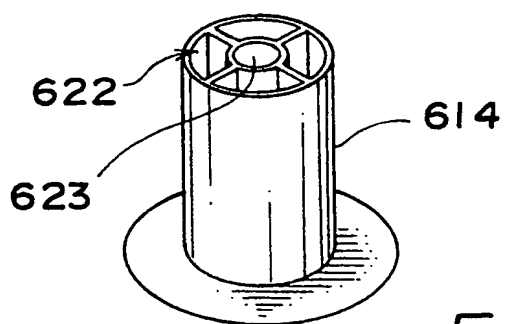
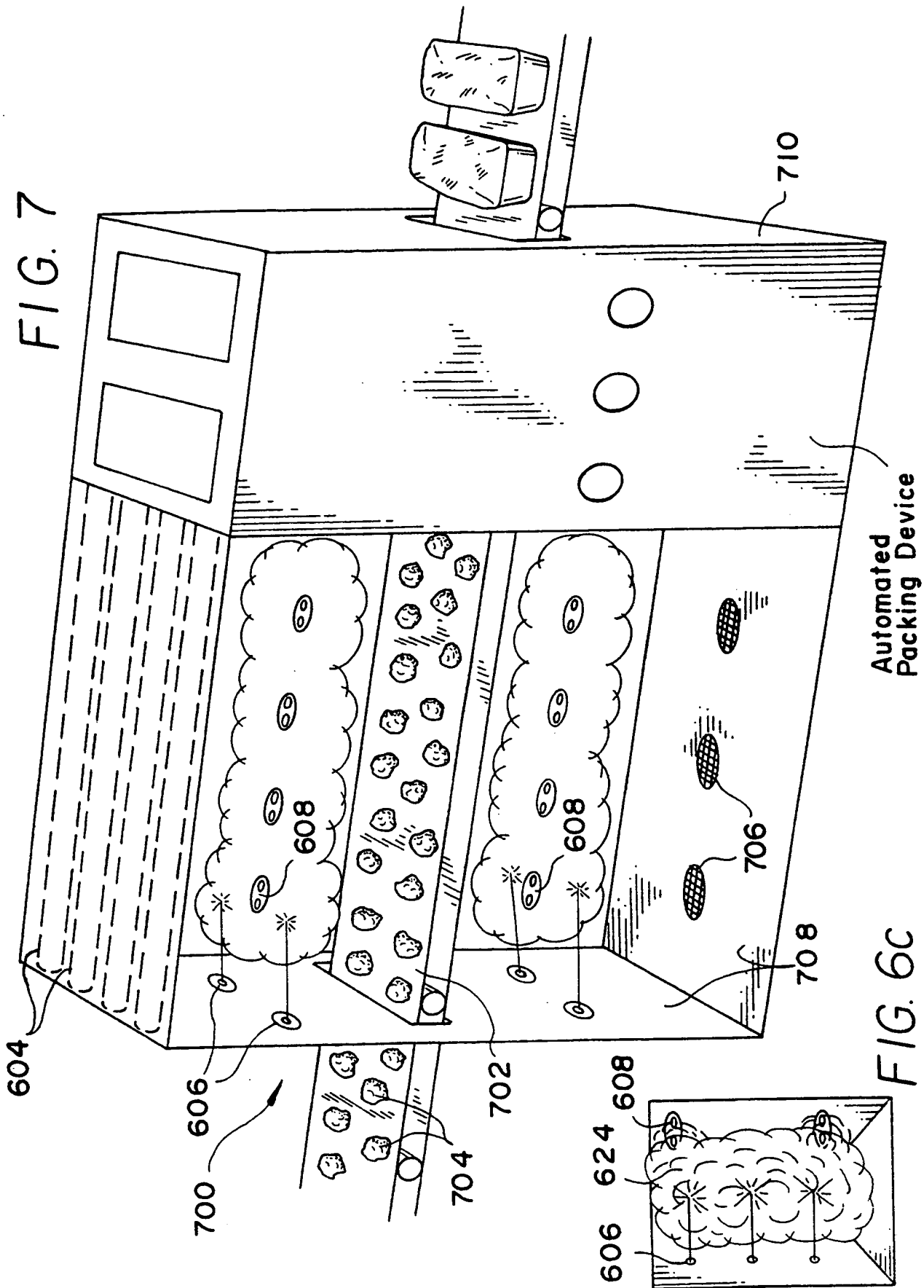


FIG. 6b

FIG. 7



Automated Packing Device

FIG. 6C

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/11881

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61L 2/10, 2/16

US CL :422/24, 292; 250/455.11, 461.1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 422/24, 292; 250/455.11, 461.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, CAPLUS

search terms: chromophore, uv, ultraviolet, steril?, disinfect?, sanit?

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,527,704 A (WOLF, JR. ET AL) 18 June 1996 (18.06.96), see entire document.	1-6
A, P	US 5,820,821 A (KAWAGOE ET AL) 13 October 1998 (13.10.98), see entire document.	1-6

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